DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 18 2005

Mr. Stojan Trošt
QA & RA Manager
Fotona d.d.
Stegne 7, 1210 Ljubjana
Slovenia

Re: K050293
Trade/Device Name: Fotona XP Plus Nd:YAG Family of Laser Systems
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: February 4, 2005
Received: February 14, 2005

Dear Mr. Trošt:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Miriam C. Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Appendix F : Indications for Use Statement

510(k) Number (if known): K 050293

Device Name: **Fotona XP Plus Nd:YAG Family of Laser Systems**

Indications For Use:

Removal of unwanted hair, for stable long term or permanent hair reduction and for treatment of PFB. The lasers are indicated on all skin types Fitzpatrick I-VI including tanned skin.

Photocoagulation and hemostasis of pigmented and vascular lesions, such as but not limited to port wine stains, hemoangioma, warts, telangiectasia, rosacea, Venus lake, leg veins and spider veins.

Coagulation and hemostasis of soft tissue.

Incision/excision of soft body tissue in dermatology

Soft tissue general surgery applications-skin incision; tissue dissection; compelte or partial resection of internal organs, tumors, lesions; tissue ablation; vessel coagulation.

Benign pigmented lesions such as, but not limited to, lentigos (age spots), solar lentigos (sun spots), café au lait macules, seborrheic keratosis, nevi, chloasma, verrucae, skin tags, keratosis, tattoos (significant reduction in the intensity of black and/or blue-black tatoos) and plaques. The laser is indicated for pigmented lesions to reduce lesion size, for patients with lesions that would potentially benefit from aggressive treatment, and for patients with lesions that have not responded to other laser treatments. The laser is also indicated for the reduction of red pigmentation and hypertrophic and keloid scars where vascularity is an integral part of the scar.

Treatment of wrinkles.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use ___
(Per 21 CFR 801.109)

K 050293

Appendix E : Summary of Safety and Effectiveness Data

3/18/05

I. General Information

Company :	Fotona d.d. Stegne 7, 1210 Ljubljana SLOVENIA
Contact Person :	Stojan Trošt
Preparation Date :	01-24-05
Device Trade Names :	Fotona XP Plus Nd:YAG Family of Laser Systems Fotona Dualis XP Plus Nd:YAG Family of Laser Systems
Common Name :	Nd:YAG Pulsed Surgical Laser System
Classification Name :	Instrument, Surgical, Powered, Laser 79-GEX 21 CFR 878-48

II. Description

The Fotona XP Plus Nd:YAG Family of Laser Systems is a flashlamp-excited, Nd:YAG (Neodymium-doped Yttrium Aluminum Garnet) laser. Pulsed laser energy at a nominal wavelength of 1064 nanometers (nm) is used. This wavelength causes maximum energy absorption by the target (hair or lesion) and minimum absorption by surrounding skin structures. In addition, the laser pulse duration is controlled to be equal to or shorter than the relaxation time of the target, to minim ize heat transfer to surrounding tissues.

Within the system, an optical cavity contains the Nd:YAG crystal, which is activated by means of the use of flashlamps. After the cavity, a red diode aiming beam is reflected onto a coaxial beam path using a beamsplitter assembly. The combined therapeutic and aiming beams are guided down an optical fiber delivery system to a focusing handpiece. The laser is used in non-contact mode. The Fotona XP Plus Nd:YAG Family of Laser Systems is designed with 5 major sub-systems:

a) A high voltage power supply which converts and rectifies the a.c. mains current to provide regulated power for the flashlamp simmer current and main triggering pulse.

b) A cooling system consisting of an internal water flow circuit together with water-to-air heat exchanger.

c) An Nd:YAG laser rod, capable of generating optical pulses .

d) An optical delivery system, interfacing the energy from the laser to the patient via an optical fiber and focusing handpiece.

e) The microprocessor based controller which regulates the functions of the laser and allows parameter selection by the user.

Accessories available for use with the Fotona XP Plus :

- Handpiece defining 2-20 mm spot sizes
- MedArt Scanner
- Fotona scanner

Fotona strongly recommends using a skin cooling during the treatment (gel, cold packs, cold air, cryogen cooling, contact cooling etc.).

III. Indications for Use

The Fotona XP Plus Nd:YAG Family of Laser Systems is intended for:

Removal of unwanted hair, for stable long term or permanent hair reduction and for treatment of PFB. The lasers are indicated on all skin types Fitzpatrick I-VI including tanned skin.

Photocoagulation and hemostasis of pigmented and vascular lesions, such as but not limited to port wine stains, hemoangioma, warts, telangiectasia, rosacea, Venus lake, leg veins and spider veins.

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Treatment of wrinkles.

III. Summary of Substantial Equivalence

The Fotona XP Plus Nd:YAG Family of Laser Systems shares the same general indications for use, operating principles, mechanism of action, technological features as the predicate devices Candela GentleYAG Family of Laser Systems (K033172), Family of Altus Medical CoolGlide Aesthetic Lasers (K023954, K022226) and Fotona Dualis XP Plus (K002839) and therefore is substantially equivalent to the predicate devices.

Technologically, the predicate devices have similar characteristics to the Fotona XP Plus Nd:YAG Family of Laser Systems . All systems comprise a flashlamp pumped Nd:YAG laser rod generating light at a wavelength of 1064 nm, which is subsequently delivered to the patient via an optical fiber delivery system and focusing handpiece.

The risk and benefits for the Fotona XP Plus Nd:YAG Family of Laser Systems are comparable to the predicate devices when used for similar clinical applications.

The Fotona XP Plus Nd:YAG Family of Laser Systems shares the same design features (wavelength, active medium, cooling system, power supply, beam deliveries, controls, housing) as the predicate devices. The output characteristics are the same as those of the predicate devices.

All lasers utilize class I aiming beams which pose no hazard to the user.

All systems are microprocessor controlled devices. The microprocessor control regulates normal operation, permits parameter selection and avoids hazard incidence.

All systems utilize an internal closed loop water-air heat exchanger circuit for optimal thermal control of the laser cavity.

The risk and benefits for the Fotona XP Plus Nd:YAG Family of Laser Systems system are identical to the predicate devices when used for similar clinical applications.

It is therefore believed that there are no new questions of Safety or Effectiveness raised by the introduction of this device.

As the Fotona XP Plus Nd:YAG Family of Laser Systems is substantially equivalent with respect to indication for use, output characteristics, materials, method of operation, and physical construction to the predicate devices, we believe it clearly meets the requirements for substantial equivalence according to Section 510(k) guidelines. Safety and effectiveness are reasonably assured, therefore justifying 510(k) clearance for commercial sale.